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14. ABSTRACT [Approximately 200 word summary of the most significant finding during the research period]
Our intent has been to identify African American males diagnosed with prostate cancer between the ages of 40 and 75 and registering them along with their at risk relatives into a program of cancer education, cancer screening, and early intervention to reduce disparities in prostate cancer incidence and mortality rates in the African American community in Nebraska and Mississippi. Family history of prostate and other cancers is being recorded with the purpose of identifying any hereditary prostate cancer syndrome. This will be possible through the recruitment of a total of 800 African Americans who have been diagnosed with prostate cancer, through recruitment activities and screenings in Omaha, Nebraska, and Jackson, Mississippi. The most significant work during the first two years of this grant has involved (1) hiring and training of culturally competent research personnel; (2) the establishment of a project-specific database; (3) recruitment of research participants and (4) data collection and pedigree development. Progress has been made in all four objectives. Although recruitment has been slow and challenging at both study sites, significant progress has been made.

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Introduction

Our intent has been to identify African American males diagnosed with prostate cancer between the ages of 40 and 75 and to enter them along with their at risk relatives into a program of cancer education, cancer screening, and early intervention to reduce disparities in prostate cancer incidence and mortality rates in the African American community in Nebraska and Mississippi. Family history of prostate and other cancers is being recorded with the purpose of identifying any hereditary prostate cancer syndrome. In addition, social and behavioral determinants are collected and recorded during the interview process for the final analysis. This will be possible through the recruitment of a total of 800 African Americans who have been diagnosed with prostate cancer, through recruitment activities and screenings in Omaha, Nebraska, and Jackson, Mississippi.

Body

Task 1: Participant Identification and Access (Years 1- 3)

At Creighton University, recruitment of subjects has been through cooperation with local urologists as well as through promotion to the community by study personnel's appearance on two local television programs that target the African American community, Real Talk and Healthy Choices on Omaha CTI22; attendance at local health fairs; publication of an article about the study in *Omaha Star* newspaper serving the Omaha African American community; an announcement of the study emailed to all online subscribers of the *Omaha World Herald* newspaper; an advertisement on the study emailed to all Creighton University physicians in their monthly School of Medicine newsletter; creation of a billboard to be displayed in an area close to North East Omaha where over 90% of African Americans reside throughout September 2012; compilation of lists of church leaders and secretaries and neighborhood watch leaders received an email or written study invitations to share with their communities; and multiple barber shop blitz was held in 2013 wherein local barbers agreed to speak to each of their clients about prostate cancer and informed them of our study and to contact our team if interested in participating.

Recruitment in Mississippi was done in collaboration with a local African American urologist through his clinic database.

One-hundred and twenty-five participants were identified at Creighton who met the eligibility criteria. Twenty-six of these participants have been interviewed and data collected from the interviews has been entered into the study-specific database according to protocol. DNA has been collected and stored according to protocol for those eligible participants who have agreed. The remaining potential participants have received a letter introducing the study and informing them that the project coordinator will be contacting them regarding participation.

Five-hundred and thirty-seven participants were identified in Jackson, Mississippi who met the eligibility criteria. Sixty-seven of these participants have been interviewed and data collected from the interviews and has been entered into the study-specific database. Blood samples has been collected and stored at Creighton for thirty-seven subjects. The remaining individuals have either refused participation after their interviews or were not selected for blood draw because there was no indication of familial prostate cancer.

Task 2: Data Collection and Management (Years 1- 3)

The study-specific database has been constructed, including onscreen instructions for its use. As stated above, data collection has been completed at Creighton and Jackson State University.

The database variables on social and behavioral determinants and risk exposure pathways suggested by the community partners were added to the database with appropriate quality controls incorporated into the program.

Task 3. Prostate Cancer Prevention and Health Education and Referral (Years 1.5-3)

Screening interviews are ongoing at both study sites, with participants positive for prostate cancer family history being identified and receiving appropriate education, genetic counseling, and/or referral. During each interview the research coordinator identifies at risk family members and encourages the participant to discuss their risk with them as well as our screening recommendations. The participant can also ask the family member to call the research coordinator directly to discuss their risk and the recommendations. The Jackson State University team developed and gave a presentation to a prostate cancer support group at their meeting on July 19, 2011. This presentation has been shared with the Creighton University Community Engagement Team. The CU project coordinator has attended three health fairs in the community to provide awareness of prostate cancer and recruitment material for the study.

Task 4 Biostatistical Analysis

To be completed during the one-year no-cost extension.

Challenges

However, in the drive to recruit participants, an oversight error occurred in which there was a lapse in IRB approval and five participants were erroneously interviewed. Also, erroneously, a message was sent to the DOD that no participant recruitment took place. Based on communication with Creighton University partners indicating that there were 2 participants on their records interviewed between May 6th 2013 and July 22nd 2013, the JSU team instituted a review of activities and an additional three participants were discovered to have been interviewed outside the IRB approval coverage period. While the review was ongoing, the following actions were also taken:

1. JSU and Creighton University IRB were informed and JSU IRB requested for the report on activities review when ready.
2. All research staff underwent CITI training in responsible conduct of research

3. A letter was written to the DOD detailing the errors and the JSU co-PI spoke with the DOD IRB contact on the telephone to explain the discrepancy. The team was asked to send the report with the determination of the JSU IRB when ready.
4. Steps were taken to prevent any other occurrence in the future.
5. The five subjects were re-consented with a current IRB approved consent form.

IRB approval is in place and current at both study sites.

Another challenge was the departure of Dr. Ekundayo from JSU and the resulting process to change the Co-principal Investigator at Jackson State University. The impact was a slowing down of recruitment, interviews and blood collection.

Key Research Accomplishments

- Recruitment and training of study personnel: research project coordinators at both sites as well as two graduate students at Jackson State University.
- Development of a study specific Access database with embedded quality control measures that is used at both research sites.
- A collaborative meeting between the two research groups completed in year one and year two.
- Cultural proficiency training of all study personnel both at Creighton University and at Jackson State University.
- Subject recruitment measurements implemented through television, newspaper, community events, prostate cancer support groups, billboards and emails to community and church leaders, local urologists and all active physicians in the area.
- Identification of 662 eligible participants wherein 93 were interviewed at Creighton University and Jackson State University. Their data has been entered into the database and blood samples have been collected and stored on 44 participants who were eligible and volunteered to donate the sample.

- Prostate cancer prevention and health education occurred at each interview as well as during each television broadcast and community outreach project. Jackson State University also provided an educational presentation to a prostate cancer support group.
- Prostate cancer education was also provided to students in the masters of Public Health program as part of their curriculum.

Reportable Outcomes/Conclusion

My review, perhaps over the past 1 year, indicates that on the basis of accrued genetic interpretation, the bulk of these familial/hereditary[5] inheritance patterns are consonant with an autosomal dominant mode of inheritance, although some rare autosomal recessive forms, such as in ataxia-telangiectasia, may account for a limited number of prostate cancers. One theme that seems to be significant is that having a brother affected with PC has a stronger familial component than having a father with PC. This finding is surprising it seems to have been reported in some national, as well as international studies. In 2010, Whitman et al. and Hooker et al. identified at risk loci specific to prostate cancer in African Americans. These loci may be targets to test in the future on the stored DNA samples from participants in families with familial prostate cancer from this study. (Table 1)

During the recruitment process, we noted that a substantial proportion of the participants at the Omaha study site had originally lived in Southern states in the US, and in Mississippi, in particular. Thus, we expect that there is considerable overlap in both environmental exposures and genetic backgrounds among participants at the two sites.

During the course of the recruitment phase of the prostate cancer study funded by the DOD, we constantly attempted to accumulate data on African Americans (AAs) in North Omaha, their geographic area of most concentration in Nebraska. Information on prostate cancer predisposing genes in African Americans are partially reflected in the enclosed tables which are considered to be

an important scientific area for continued study. Familial history may help us determine candidates for prostate-specific antigen (PSA) assessment. The involvement of our African American Co-PIs in both Omaha and Jackson have helped tremendously in our recruitment efforts and in the outreach to the AA community. Their efforts have been invaluable in terms of our ability to identify patients with PC in the community. However, a major concern throughout the study were the limitations involved in terms of identifying initial AA PC affected but their unwillingness, in most cases, to undergo a detailed family history assessment and, when indicated by us, to be of clinical-genetic importance with the need to follow-up with blood draws for ultimate molecular genetic investigation. We trained our staff on the value of cultural sensitivity, majority of our personnel look like the target community and we were very sensitive in our response to the questions asked by the participants. Unfortunately, some of the participants did not trust the system because of the vestiges of the Tuskegee Syphilis study that still lingers in their minds. Lack of trust, for whatever reason, resulted, we believe, in our inability to follow through with detailed family histories and ultimately lack of cooperation on the part of these AAs to allow blood draws for DNA collection and for ultimate molecular genetic involvement.

In addition, in Jackson, we faced difficulty in recruiting participants when the caller had an African, rather than a local African American, accent. This may be because it is common in Jackson for “cold calling” insurance sales people to be African and the typical response in the community is to hang up upon hearing the accent. Because of this experience, an African student’s responsibilities were then changed from working with Dr. Ekundayo on outreach to working with Dr. Buxbaum detailing family structures. Sometimes spouses were suspicious of a female caller’s reason for calling, even though packets of information had been sent including a letter from their trusted medical provider. In other cases, the reason for non-participation was not clear to the investigators, even after multiple follow-up calls. We noted that, once participants did agree to interview, it was common for participants’ affects to change from guarded at the beginning to very open and talkative by the conclusion of the interview.

To date, between the two study sites we have identified 662 eligible participants for the study through local urologists, community recruitment and the immeasurable efforts of our staff. Ninety-three individuals have been interviewed with data entered and blood samples stored for the study. Multiple recruitment measures were implemented to increase recruitment numbers and raise interest in the communities.

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Appendices

Table of prostate cancer-associated genes.